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(21) International Application Number: PCT/US96/06975 (22) International Filing Date: 28 May 1996 (28.05.96) (30) Priority Data: 08/482,579 7 June 1995 (07.06.95) US (71) Applicant: HENKEL CORPORATION [US/US]; Suite 150, 140 Germantown Pike, Plymouth Meeting, PA 19462 (US). (72) Inventors: DESAI, Suresh; 123 Chopin Drive, Wayne, NJ 07470 (US). HESSEL, John, Frederick; 20 Clarendon Court, Metuchen, NJ 08840 (US). (74) Agent: DRACH, John, E.; Henkel Corporation, Suite 150, 140 Germantown Pike, Plymouth Meeting, PA 19462 (US).		(81) Designated States: AU, BR, CA, CN, JP, KR, MX, NZ, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i>
(54) Title: IODINE COMPLEX OF ALKYL POLYGLYCOSIDES (57) Abstract An iodine complex concentrate containing (a) from about 0.5 to about 30 % by weight of iodine; (b) from about 0.2 to about 14 % by weight of an iodide component selected from the group consisting of iodide salt, iodide acid and mixtures thereof; and (c) from about 2 % to about 85 % by weight of a nonionic sugar surfactant selected from the group consisting of alkyl glucose esters, aldobionamides, gluconamides, glyceramides, glyceroglycolipids, polyhydroxy fatty acid amides, alkyl polyglycosides having the general formula (I): $R_1O(R_2O)_b(Z)_a$, wherein R_1 is a monovalent organic radical having from about 6 to about 30 carbon atoms; R_2 is divalent alkylene radical having from 2 to 4 carbon atoms; Z is a saccharide residue having 5 or 6 carbon atoms; b is a number having a value from 0 to about 12; a is a number having a value from 1 to about 6, and mixtures thereof, all weights being based on the weight of the concentrate.		

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IODINE COMPLEX OF ALKYL POLYGLYCOSIDES

Field of the Invention:

The present invention generally relates to a novel concentrate containing complexed iodine. More particularly, the present invention relates to an iodine complex concentrate for use in antimicrobial use compositions.

Background of the Invention:

Iodine compositions have long been known to impart desirable antimicrobial and non-staining characteristics. Complexed iodine compositions are known to be useful as sanitizers for elements ranging from contact surfaces and glassware to plant formulation facilities. An especially important application for iodine compositions is in clean-in-place (CIP) systems. CIP systems are generally found in industries which produce fluidized ingestible products for humans or animals such as the dairy industry, the pharmaceutical industry, and

the food industry. Clean-in-place systems are generally regarded as large production plant systems having reservoirs, pipes, pumps and mixing vessels which cannot be broken down to be cleaned. Additionally, clean-in-place preparation systems often require high sanitization when used in the production of ingestible substances.

In order to be dependable and useful to an end user, iodine compositions must be stable (i.e. remain homogeneous) over a wide range of temperature and prolonged periods of time. If stability is lost, and the products separate, the utility of the composition is significantly degraded and they can present a potential hazard to the user. Generally speaking, stability in this context means that a given product must remain completely homogeneous after extended storage at temperatures ranging from room temperature to as high as 40°C, which can occur during transport in closed vehicles. Furthermore, although a given product may separate when frozen, especially after undergoing several freeze-thaw cycles, it must be readily reconstitutable as a homogeneous mixture upon simple shaking or mixing.

Iodine-based antimicrobial use products designed for topical application to the skin are normally formulated with a certain amount of emollient. The most common emollients employed are glycerin, lanolin and its derivatives, sorbitol, fatty acid esters of polyhydroxylated compounds and propylene glycol. These emollients are used at levels ranging from below 1% to as much as 10% in use compositions. Glycerin is the most widely used emollient in bovine teat dips and is also used extensively at low levels in human topical detergent-iodine and povidone-iodine formulations. Emollients are needed because of the harshness

to skin associated with those surfactants contained in the detergent part of the composition.

Another desirable functional characteristic for iodine-based antimicrobial use compositions designed for topical application is the ability to spread evenly on the skin and not drain off so rapidly as to prevent insufficient germicidal contact time. Many of the usual ingredients in antimicrobial products contribute to viscosity. However, it is common for topical products to be formulated with a specific thickener to provide added viscosity. There are many viscosity modifiers compatible with iodine-based antimicrobial use systems, such as carboxymethylcellulose derivatives, polyacrylate derivatives, alginates, xanthates and polysaccharides. These are typically used at levels below 1% by weight in a final use composition. These types of ingredients, properly selected, have an insignificant effect on the homogeneity of a given use composition. On the other hand, where dilutable concentrates are desired, viscosity-modifying additives can become a problem and special care must be taken in the selection of specific agents and their levels of use in concentrates.

The prior art is replete with examples of antimicrobial use formulations having relatively high detergent/average available iodine ratios in excess of 5:1. There are, however, a number of potential advantages associated with the use of very low detergent/average available iodine ratios in germicidal iodine concentrates and use compositions designed for skin or tissue application. For example, in a low ratio product of this type, there would be less organic matter to react with the iodine, thereby rendering such compositions more stable relative to the normal high ratio of detergent to average available iodine content. Another

advantage is that reduced amounts of detergent would be expected to be less irritating to the skin and would accordingly require a lesser amount of emollient. Compositions with lower detergent/average available iodine ratios could be formulated to have higher, and more stable, free or uncomplexed iodine levels.

5 The use of minimal amounts of detergent also would allow for the possibility of reduced water content in concentrates, thereby correspondingly reducing packaging, shipment and storage costs. However, one obvious disadvantage associated with these types of formulations is that lower amounts of detergent component reduce the deterative effectiveness of the germicidal composition.

10 Moreover, the use of lower ratios of detergent/average available iodine also results in the composition becoming less storage stable which makes them significantly less marketable.

Accordingly, it is an object of the present invention to provide iodine complex concentrate designed for topical applications onto both human and
15 animal skin that employs a component acting as both a complexing agent for the iodine, and a mild yet effectively deterative surfactant which is less harsh on skin and tissue, thereby requiring the addition of little if any emollients to the antimicrobial use composition.

It is another object of the present invention to provide an iodine complex
20 concentrate for use in antimicrobial use compositions to disinfect and sanitize various contact surfaces including those present in CIP systems, as well as glassware which is capable of being employed at relatively high detergent/average available iodine ratios, thus making the formulated antimicrobial compositions more storage stable over prolonged time periods and

temperature ranges while imparting maximum detergent properties.

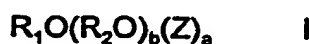
Summary of the Invention:

The present invention overcomes the problems outlined above by providing a stable iodine complex concentrate for use in various aqueous antimicrobial use compositions. Accordingly, the present invention provides an iodine complex concentrate containing:

(a) from about 0.5 to about 30% by weight of iodine;

(b) from about 0.2 to about 14% by weight of a component selected from the group consisting of iodide salt, iodide acid and mixtures thereof; and

(c) from about 2.0 to about 85% by weight of a nonionic sugar surfactant selected from the group consisting of alkyl glucose esters, aldobionamides, gluconamides, glyceramides, glyceroglycolipids, polyhydroxy fatty acid amides, alkyl polyglycosides having the general formula I:



wherein R_1 is a monovalent organic radical having from about 6 to about 30 carbon atoms; R_2 is divalent alkylene radical having from 2 to 4 carbon atoms; Z is a saccharide residue having 5 or 6 carbon atoms; b is a number having a value from 0 to about 12; a is a number having a value from 1 to about 6, and mixtures thereof, all weights being based on the weight of the concentrate.

The present invention also provides an aqueous antimicrobial use composition containing the above-disclosed iodine complex concentrate and a diluent.

The present invention also provides a process for cleaning, disinfecting

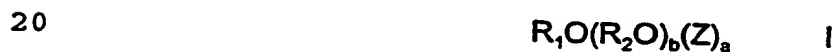
and sanitizing an intended surface involving contacting the intended surface with the above-disclosed aqueous antimicrobial use composition.

Description of the Invention:

Other than in the operating examples, or where otherwise indicated, all numbers expressing quantities of ingredients or reaction conditions used herein are to be understood as modified in all instances by the term "about".

The foregoing and other related objects are achieved, and the disadvantages of the prior art are obviated by the surprising discovery that a nonionic sugar surfactant effectively functions as both a complexing agent for iodine in iodine complex concentrates and a mild, yet deterative surfactant when the iodine complex concentrates are diluted to form an aqueous antimicrobial use composition. The term nonionic sugar surfactant as used herein refers to surfactants that are based on saccharide moieties. The nonionic sugar surfactants which may be employed in the present invention are selected from the group consisting of alkyl polyglycosides, alkyl glucose esters, aldobionamides, gluconamides, glyceramides, glyceroglycolipids, polyhydroxy fatty acid amides, and mixtures thereof.

Preferred alkyl polyglycosides which can be used as the complexing agent in the concentrate of the invention have the formula I:



wherein Z is a glucose residue and b is zero. Such alkyl polyglycosides are commercially available, for example, as GLUCOPON®, or PLANTAREN® surfactants from Henkel Corporation, Ambler, PA., 19002. Examples of such surfactants include but are not limited to:

1. GLUCOPON® 225 Surfactant - an alkyl polyglycoside in which the alkyl group contains 8 to 10 carbon atoms and having an average degree of polymerization of 1.7.
2. GLUCOPON® 425 Surfactant - an alkyl polyglycoside in which the alkyl group contains 8 to 16 carbon atoms and having an average degree of polymerization of 1.6.
3. GLUCOPON® 625 Surfactant - an alkyl polyglycoside in which the alkyl groups contains 12 to 16 carbon atoms and having an average degree of polymerization of 1.6.
4. APG® 325 Surfactant - an alkyl polyglycoside in which the alkyl groups contains 9 to 11 carbon atoms and having an average degree of polymerization of 1.6.
5. GLUCOPON® 600 Surfactant - an alkyl polyglycoside in which the alkyl groups contains 12 to 16 carbon atoms and having an average degree of polymerization of 1.4.
6. PLANTAREN® 2000 Surfactant - a C₈₋₁₆ alkyl polyglycoside in which the alkyl group contains 8 to 16 carbon atoms and having an average degree of polymerization of 1.4.
7. PLANTAREN® 1300 Surfactant - a C₁₂₋₁₆ alkyl polyglycoside in which the alkyl groups contains 12 to 16 carbon atoms and having an average degree of polymerization of 1.6.

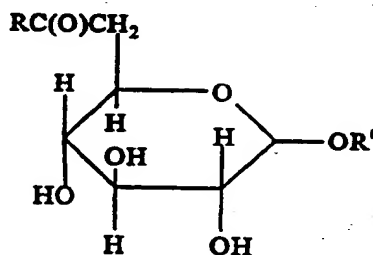
Other examples include alkyl polyglycoside surfactant compositions which are comprised of mixtures of compounds of formula I wherein Z represents a moiety derived from a reducing saccharide containing 5 or 6 carbon atoms; a is

a number having a value from 1 to about 6; b is zero; and R₁ is an alkyl radical having from 8 to 20 carbon atoms. The compositions are characterized in that they have increased surfactant properties and an HLB in the range of about 10 to about 16 and a non-Flory distribution of glycosides, which is comprised of a mixture of an alkyl monoglycoside and a mixture of alkyl polyglycosides having varying degrees of polymerization of 2 and higher in progressively decreasing amounts, in which the amount by weight of polyglycoside having a degree of polymerization of 2, or mixtures thereof with the polyglycoside having a degree of polymerization of 3, predominate in relation to the amount of monoglycoside, said composition having an average degree of polymerization of about 1.8 to about 3. Such compositions, also known as peaked alkyl polyglycosides, can be prepared by separation of the monoglycoside from the original reaction mixture of alkyl monoglycoside and alkyl polyglycosides after removal of the alcohol. This separation may be carried out by molecular distillation and normally results in the removal of about 70-95% by weight of the alkyl monoglycosides. After removal of the alkyl monoglycosides, the relative distribution of the various components, mono- and poly-glycosides, in the resulting product changes and the concentration in the product of the polyglycosides relative to the monoglycoside increases as well as the concentration of individual polyglycosides to the total, i.e. DP2 and DP3 fractions in relation to the sum of all DP fractions. Such compositions are disclosed in U.S. patent 5,266,690, the entire contents of which are incorporated herein by reference.

Other alkyl polyglycosides which can be used in the compositions according to the invention are those in which the alkyl moiety contains from 6 to

18 carbon atoms in which and the average carbon chain length of the composition is from about 9 to about 14 comprising a mixture of two or more of at least binary components of alkylpolyglycosides, wherein each binary component is present in the mixture in relation to its average carbon chain length in an amount effective to provide the surfactant composition with the average carbon chain length of about 9 to about 14 and wherein at least one, or both binary components, comprise a Flory distribution of polyglycosides derived from an acid-catalyzed reaction of an alcohol containing 6-20 carbon atoms and a suitable saccharide from which excess alcohol has been separated. The alkyl polyglycoside of the present invention acts as the complexing agent for the iodine complex concentrate.

The alkyl glucose ester sugar surfactants are generally disclosed in U.S. patent Nos. 5,109,127 and 5,190,747 the entire contents of both of which are incorporated herein by reference. These sugar surfactants have the general formula II:

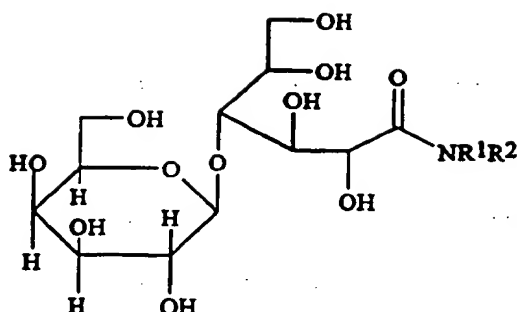


wherein R represents a fatty acid residue of 6 to 20 carbon atoms, preferably 6 to 12 carbon atoms and R¹ represents an alkyl group having 2 to 6 carbon atoms. Representative examples of such alkyl glucose esters are 1-ethyl-6-caprylglucoside, 1-ethyl-6-laurylglucoside, 1-butyl-6-caprylglucoside, 1-ethyl-6-palmitylglucoside and 1-ethyl-6-oleylglucoside.

The aldobionamide sugar surfactants are generally disclosed in U.S. Patent No. 5,310,542 and in published European Patent Application No. 550,281 both of which are incorporated herein by reference. An Aldobionamide is generally defined as the amide of an aldobionic acid or aldobionolactone and an aldobionic acid in turn is defined as a sugar substance (e.g. any cyclic sugar) in which the aldehyde group has been replaced by a carboxylic acid which upon drying is capable of cyclizing to form an aldonolactone. The aldobionamides can be based on compounds comprising two saccharide units, e.g. lactobionamides, maltobionamides, cellobionamides, melibionamides, or gentiobionamides, or they can be based on compounds comprising more than two saccharide units provided that the polysaccharide has a terminal sugar unit with an aldehyde group available.

The preferred aldobionamides of the present invention are lactobionamides of the formula III:

11



wherein R^1 and R^2 are the same or different and are selected from hydrogen and an aliphatic hydrocarbon radical containing up to about 36 carbon atoms (e.g. alkyl groups and alkenyl groups which groups may also include a heteroatom such as N, O, S, present, for instance, as an amide, carboxy, ether and/or saccharide moiety) except that R^1 and R^2 cannot simultaneously be hydrogen. The aliphatic hydrocarbon radical preferably contains up to 24 carbon atoms, most preferably from 8 to 18 carbon atoms. Representative examples of such lactobionamides are N-propyl lactobionamide, N-pentyl lactobionamide, N-decyl lactobionamide, N-hexadecyl lactobionamide, N-oleyl lactobionamide, N-dodecyl-N-methyl lactobionamide, and N-dodecyloxypropyl lactobionamide.

The gluconamide sugar surfactants are generally disclosed in U.S. Patent 5,352,386 the entire contents of which is incorporated herein by reference. These surfactants have the general formula IV:



wherein m is an integer from 2 to 5; and R is a straight or branched, saturated or unsaturated aliphatic hydrocarbon having 4 to about 24 carbon atoms,

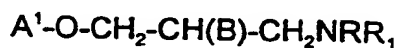
preferably 8 to 24 carbon atoms, which R group can also contain a heteroatom selected from the group consisting of oxygen, nitrogen and sulfur. Representative examples of such cosurfactants are N-octylerythronamide, N-decylerythronamide, N-dodecylerythronamide, N-tetradecylerythronamide, N-decylxylonamide and N-dodecylxylonamide.

The glyceramide sugar surfactants are generally disclosed in U.S. Patent 5,352,387 the entire contents of which is incorporated herein by reference. These cosurfactants have the general formula V:



wherein R is a C₈ to C₂₄ straight or branched chained, saturated or unsaturated aliphatic hydrocarbon in which the R group may also be substituted by a heteroatom selected from oxygen, nitrogen and sulfur. Representative examples of such cosurfactants are N-octylglyceramide, N-decylglyceramide and N-hexadecylglyceramide.

The glyceroglycolipid sugar surfactants are generally disclosed in U.S. Patent 5,358,656, and published European Patent Application No. 550,279 the disclosure of each of which is incorporated herein by reference. The glyceroglycolipids can be of the formula VI:



wherein A¹ is a saccharide, preferably having one or more saccharide units, more

preferably a mono or disaccharide and most preferably a monosaccharide such as glucose or galactose; R and R₁ are the same or different and are hydrogen, a branched or unbranched hydrocarbon radical having from 1 to about 24, preferably from about 6 to about 18 carbon atoms; B is OH or a NR²R³ group, wherein R² and R³ may be the same or different and are hydrogen, a branched or unbranched hydrocarbon radical having 1 to 24, preferably from 6 to 18 carbon atoms, and NRR₁ and B are positionally interchangeable. Representative examples of such cosurfactants are 3-(butylamino)-2-hydroxypropyl-β-D-galactopyranoside, 3-(octylamino)-2-hydroxypropyl-β-D-galactopyranoside, 3-(eicosylamino)-2-hydroxypropyl-β-D-galactopyranoside, 3-(butylamino)-2-hydroxypropyl-β-D-glucopyranoside, and 3-(pentylamino)-2-hydroxypropyl-β-D-mannopyranoside.

Other glyceroglycolipid surfactants are disclosed in published European Patent Application No. 550,280 which is incorporated herein by reference. These cosurfactants are of the formula VII:



wherein A¹ is from 1 to 4 saccharide units and more preferably represents a mono or disaccharide, and most preferably a monosaccharide, for example, glucose or galactose; R and R₁ are the same or different and are hydrogen, or a branched or unbranched, saturated or unsaturated, hydrocarbon radical having from 1 to 24 carbon atoms, preferably from 6 to 18 carbon atoms. Representative examples of such cosurfactants are 3-(butyloxy)-2-hydroxypropyl-β-D-

galactopyran side, 3-(eicosyloxy)-2-hydroxypropyl- β -D-galactopyranoside, 3-(decyloxy)-2-hydroxypropyl- β -D-galactopyranoside, 3-(butyloxy)-2-hydroxypropyl- β -D-glucopyranoside, 3-(octyloxy)-2-hydroxypropyl- β -D-mannopyranoside, 3-(tetradecyloxy)-2-hydroxypropyl- β -D-lactoside, 3-(octadecyloxy)-2-hydroxypropyl- β -D-maltoside, 3-(octyloxy)-2-hydroxypropyl- β -D-galactotrioside, and 3-(dodecyloxy)-2-hydroxypropyl- β -D-celotrioside.

The polyhydroxy fatty acid amide sugar surfactants are generally disclosed in U.S. Patent Nos. 5,174,927, 5,223,179 and 5,332,528 the entire disclosure of each of which is incorporated herein by reference. The polyhydroxy fatty acid amide surfactant component of the present invention comprises compounds of the structural formula VIII:



wherein: R^1 is H, C_1 - C_4 hydrocarbyl, 2-hydroxy ethyl, 2-hydroxy propyl or a mixture thereof, preferably C_1 - C_4 alkyl, more preferably C_1 or C_2 alkyl, most preferably C_1 alkyl (i.e., methyl); and R^2 is a C_5 - C_{31} hydrocarbyl, preferably straight chain C_7 - C_{19} alkyl or alkenyl, more preferably straight chain C_9 - C_{17} alkyl or alkenyl, most preferably straight chain C_{11} - C_{17} alkyl or alkenyl, or mixture thereof; and Z is a polyhydroxyhydrocarbyl having a linear hydrocarbyl chain with at least 3 hydroxyls directly connected to the chain, or an alkoxylated derivative (preferably ethoxylated or propoxylated) thereof. Z preferably will be derived from a reducing sugar in a reductive amination reaction; more preferably Z is a glyceryl. Suitable reducing sugars include glucose, fructose, maltose, lactose, galactose,

mannose, and xylose. As raw materials, high dextrose corn syrup, high fructose corn syrup, and high maltose corn syrup can be utilized as well as the individual sugars listed above. These corn syrups may yield a mix of sugar components for Z. It should be understood that it is by no means intended to exclude other suitable raw materials. Z preferably will be selected from the group consisting of

5 $-\text{CH}_2-(\text{CHOH})_n-\text{CH}_2\text{OH}$, $-\text{CH}(\text{CH}_2\text{OH})-(\text{CHOH})_{n-1}-\text{CH}_2\text{OH}$, $-\text{CH}_2-(\text{CHOH})_2(\text{CHOR}')(\text{CHOH})-\text{CH}_2\text{OH}$, where n is an integer from 3 to 5, inclusive, and R' is H or a cyclic or aliphatic monosaccharide, and alkoxyated derivatives thereof. Most preferred are glycityls wherein n is 4, particularly

10 $-\text{CH}_2-(\text{CHOH})_4-\text{CH}_2\text{OH}$.

In the above Formula R¹ can be, for example, N-methyl, N-ethyl, N-propyl, N-isopropyl, N-butyl, N-2-hydroxy ethyl, or N-2-hydroxy propyl.

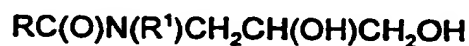
R²C(O)N< can be, for example, cocamide, stearamide, oleamide, lauramide, myristamide, capricamide, palmitamide, tallowamide, etc.

15 Z can be 1-deoxyglucityl, 2-deoxyfructityl, 1-deoxymaltityl, 1-deoxylactityl, 1-deoxygalactityl, 1-deoxymannityl, 1-deoxymaltotriosityl, etc.

Representative examples of such surfactants are N-methyl-N-1-deoxyglucityl cocoamide and N-methyl-N-1-deoxyglucityl tallowamide.

Other suitable polyhydroxy fatty acid amide surfactants (see U.S. Patent

20 Nos. 5,223,179 and 5,338,491, the entire contents of each which are incorporated herein by reference) are those of the formula IX:



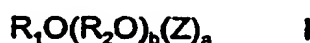
wherein R is a C₇-C₂₁ hydrocarbyl species, i.e., coconut, tallow, palm fatty alkyl and oleyl, and R¹ is a C₁ to C₆ hydrocarbyl or substituted hydrocarbyl species, i.e., N-alkyl-N-(1,2-propanediol) and N-hydroxyalkyl-N-1,2-propanediol fatty acid amides. Representative examples of such cosurfactants are the tallow amide of 3-[2-(hydroxyethyl)amino]-1,2-propanediol (HEAPD), the palmitate amide of 3-methylamino-1,2-propanediol (MAPD) and the lauramide of MAPD.

The function of the iodine in the present invention is to provide disinfecting and sanitizing antimicrobial efficacy. Iodine is generally chosen over other elemental disinfecting and sanitizing agents due to its high antimicrobial efficacy over short periods of time.

Iodine is a nonmetallic element belonging to the halogen family in Group VIIA of the periodic table. It is the heaviest common member of this family and the only one that is solid at ambient temperatures. Iodine, like other halogens, is very active chemically, but more desirable than other halogens as being less violent in its action. Iodine is slightly soluble in water, the solubility increasing with temperature. Iodine also dissolves in many organic solvents.

The iodine component of the present invention is derived from two sources, i.e., from both iodine itself and an iodide constituent such as sodium iodide, potassium iodide or hydroiodic acid, and, optionally, water. Generally, the amount of available iodine present in the iodine complex concentrate of the invention ranges from about 200 to about 20,000 ppm iodine. Also, the weight ratio of nonionic sugar surfactant acting as complexing agent to available iodine in the concentrate ranges from about 6:1 to about 1:1, respectively, and is preferably about 4:1.

In a preferred embodiment of the present invention, the iodine complex concentrate of the present invention contains from about 5 to about 20 % by weight of iodine, from about 0.2 to about 14% by weight of iodide salt, and from about 2.0 to about 85% by weight of an alkyl polyglycoside having the general formula I:



wherein R_1 is a monovalent organic radical having from about 6 to about 30 carbon atoms; R_2 is divalent alkylene radical having from 2 to 4 carbon atoms; Z is a saccharide residue having 5 or 6 carbon atoms; b is a number having a value from 0 to about 12; a is a number having a value from 1 to about 6, and mixtures thereof, all weights being based on the weight of the concentrate. It should also be noted that the formed iodine complex concentrate of the present invention may be either in liquid or solid, i.e., powder, form.

The iodine complex concentrate of the present invention may be diluted with a diluent such as water to form an aqueous antimicrobial use composition. Aqueous antimicrobial use compositions are well known in the art and are employed for a variety of uses such as in clean-in-place (CIP) systems used in industries which produce fluidized ingestible products for humans or animals such as the dairy industry, the pharmaceutical industry and the food industry, to clean contact surfaces and glassware. Aqueous antimicrobial compositions are also well known for their use in topical skin applications to clean, disinfect and sanitize both human and animal skin. Topical aqueous antimicrobial use compositions are primarily used as pre-operative antiseptic preparations, hand

cleaners and in bovine teat dips for mastitis prevention.

Thus, the present invention provides an antimicrobial use composition resulting from the dilution of the iodine complex concentrate of the present invention to an available iodine content level of from about 0.5 to about 200 ppm iodine. The diluent employed is typically water, although any other type of desirable diluent may also be used. Similarly, the specific amount of diluent to be employed will depend on the particular use of the antimicrobial use composition. In general, however, the amount of diluent used should be sufficient to form an antimicrobial use composition having an available iodine content level of from about 0.5 to about 200 ppm iodine, as stated above. It should also be noted that while the nonionic sugar surfactant primarily acts as a complexing agent for iodine, it also acts as a deterative surfactant. Thus, if it is desired to enhance the cleaning efficacy of an aqueous antimicrobial use composition, additional surfactants may also be employed in the formulation of either the iodine complex concentrate or the aqueous antimicrobial use composition. Examples of suitable surfactants include anionics, nonionics, cationics, amphoterics, zwitterionics and mixtures thereof. Additional additives may also be employed when formulating either the iodine complex concentrate or the aqueous antimicrobial use composition such as fragrances, dyes, fillers, viscosity modifiers, foam regulators or additional complexing agents.

The present invention also provides a process for cleaning, disinfecting and sanitizing various intended surfaces. Examples of intended surfaces include both human and animal skin, as well as contact surfaces such as those present in clean-in-place (CIP) systems used to produce fluidized ingestible products as

well as glassware. In general, however, any surface which requires cleaning, disinfecting and sanitizing qualifies as an intended surface. The process involves contacting the intended surface with the above-described aqueous antimicrobial use composition.

5 The present invention will be better understood from the examples which follow, all of which are intended to be illustrative only and not meant to unduly limit the scope of the invention. Unless otherwise indicated, percentages are on a weight-by-weight basis.

Example 1

10 An iodine complex concentrate composition was prepared having the following formulation.

	<u>Component</u>	<u>%/wt</u>
	(a) GLUCOPON® 325	79.0
	(b) Nal	6.8
15	(c) Iodine (crystals)	<u>14.2</u>
		100.0

Nal was added to the alkyl polyglycoside with stirring and the mixture was then stirred for an additional 25 minutes. The iodine crystals were then added to the mixture in increments with stirring, and then this mixture was stirred for an
20 additional 4 hours at room temperature. The mixture was then heated to from 35 to 40°C and held at that temperature for approximately 30 minutes with stirring to form the iodine complex concentrate composition.

Example 2

An iodine complex concentrate composition was prepared as in Example

1 having the following formulation.

	<u>Component</u>	<u>%/wt</u>
	(a) GLUCOPON® 425	83.8
	(b) NaI	5.2
	(c) Iodine (crystals)	<u>11.0</u>
5		100.0

Example 3

An iodine complex concentrate composition was prepared as in Example 1 having the following formulation.

	<u>Component</u>	<u>%/wt</u>
10	(a) GLUCOPON® 600	60.6
	(b) NaI	5.2
	(c) Iodine (crystals)	11.0
	(d) Deionized water	<u>23.2</u>
		100.0

Example 4

An iodine complex concentrate composition was prepared as in Example 1 having the following formulation.

	<u>Component</u>	<u>%/wt</u>
	(a) GLUCOPON® 225	47.0
20	(b) NaI	5.2
	(c) Iodine (crystals)	11.0
	(d) Deionized water	<u>36.8</u>
		100.0

Table 1 summarizes the initial iodine content of the Examples at a temperature of 25°C.

Table 1

Exs.	AI at 25°	TI at 25°	Theor. value AI	Theor. value TI	% yield Iodine AI	% yield Iodine TI
1	12.8	20.6	14.3	21	89.5	98.0
2	9.5	15.7	10.0	16.2	95.0	96.93
3	9.7	15.5	11.0	16.2	88.2	95.6
4	9.9	15.4	11.0	16.2	90.0	95.0
C1*	21.2	27.2	22.0	31.0	96.3	88.1

*C1 = BIOPAL® NR 20, a nonylphenoxy poly (ethylenoxy) ethanol iodine complexing agent available from Rhone-Poulenc, Cranbury, NJ 08512.

AI = available iodine

TI = total iodine

Table 2 summarizes the iodine content of the Examples at a temperature of 25°C and 50°C after a storage period of 9 weeks.

Table 2

Exs.	AI at 25°/50°	TI at 25°/50°	Theor. value AI	Theor. value TI	% yield Iodine AI	% yield Iodine TI
1	13.0/12.3	21.0/20.8	14.3	21	90.9/86.0	100/99.0
2	9.4/8.7	15.7/16.1	10.0	16.2	94.0/87.0	97.0/99.3
3	9.7/12.1	16.0/21.0	11.0	16.2	88.2/—	98.7/—
4	10.0/9.3	15.7/15.8	11.0	16.2	90.9/84.5	97.0/97.5
C1*	21.1/20.9	26.9/16.6	22.0	31.0	96.3/95.0	87.0/86

*C1 = BIOPAL® NR 20 is a nonylphenoxy poly (thylenoxy) ethanol iodine complexing agent available from Rhone-Poulenc, Cranbury, NJ 08512.

AI = available iodine
TI = total iodine

Example 5

5 An aqueous antimicrobial use formulation for topical skin application was prepared using the iodine complex concentrate prepared in Example 1 having the following formulation.

	<u>Component</u>	<u>%/wt</u>
	(a) Iodine complex of Ex. 1	18.4
	(b) GLUCOPON® 325	25.0
10	(c) 70% H ³ PO ₄	36.0
	(c) Propylene Glycol	8.0
	(d) Deionized water	<u>12.6</u>
		100.0

15 Table 3 summarizes the stability results of Example 5 obtained after one week of storage, at a temperature of 25°C.

Table 3

	Theoretical	Actual
AI	2.43	2.44
TI	3.72	3.63

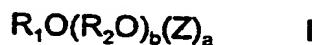
What is claimed is:

1. An iodine complex concentrate comprising:

(a) from about 0.5 to about 30% by weight of iodine;

5 (b) from about 0.2 to about 14% by weight of an iodide component selected from the group consisting of iodide salt, iodide acid and mixtures thereof; and

10 (c) from about 2% to about 85% by weight of a nonionic sugar surfactant selected from the group consisting of alkyl glucose esters, aldobionamides, gluconamides, glyceramides, glyceroglycolipids, polygydroxy fatty acid amides, alkyl polyglycosides having the general formula I:



15 wherein R_1 is a monovalent organic radical having from about 6 to about 30 carbon atoms; R_2 is divalent alkylene radical having from 2 to 4 carbon atoms; Z is a saccharide residue having 5 or 6 carbon atoms; b is a number having a value from 0 to about 12; a is a number having a value from 1 to about 6, and mixtures thereof, all weights being based on the weight of the concentrate.

2. The concentrate of claim 1 wherein said nonionic sugar surfactant is said alkyl polyglycoside.

20 3. The concentrate of claim 1 wherein said iodide salt is selected from the group consisting of sodium iodide, potassium iodide and mixtures thereof.

4. The concentrate of claim 2 wherein b of said general formula I is 0.

5. The concentrate of claim 1 having an available iodine content of from about 200 to about 20,000 ppm.

6. The concentrate of claim 1 wherein said component (a) is present in an

amount f from about 5 to about 20% by weight, based on the weight of the concentrate.

7. The concentrate of claim 1 having a weight ratio of said component (c) to available iodine in said components (a) + (b) of from about 6:1 to about 1:1, respectively.

8. The concentrate of claim 7 wherein said weight ratio is 4:1.

9. The concentrate of claim 1 containing an additive selected from the group consisting of nonionics, anionics, cationics, amphoterics, zwitterionics, viscosity modifiers, fragrances, dyes, fillers, foam regulators, and mixtures thereof.

10. The concentrate of claim 1 having a pH of from about 2 to about 7.

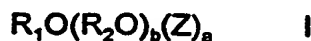
11. An aqueous antimicrobial use composition comprising an iodine complex concentrate and a diluent, said concentrate comprising:

(a) from about 0.5 to about 30% by weight of iodine;

(b) from about 0.2 to about 14% by weight of a component selected from the group consisting of iodide salt, iodide acid and mixtures thereof; and

(c) from about 2% to about 85% by weight of a nonionic sugar surfactant selected from the group consisting of alkyl glucose esters, aldobionamides, gluconamides, glyceramides, glyceroglycolipids, polygydroxy fatty acid amides, alkyl polyglycosides having the general formula I:

20



wherein R_1 is a monovalent organic radical having from about 6 to about 30 carbon atoms; R_2 is divalent alkylene radical having from 2 to 4 carbon atoms; Z is a saccharide residue having 5 or 6 carbon atoms; b is a number having a value from 0 to about 12; a is a number having a value from 1 to about 6, and

mixtures thereof, all weights being based on the weight of the concentrate.

12. The composition of claim 11 wherein said nonionic sugar surfactant is said alkyl polyglycoside.

13. The composition of claim 11 wherein said iodide salt is selected from the group consisting of sodium iodide, potassium iodide and mixtures thereof.

14. The composition of claim 12 wherein b of said general formula I is 0.

15. The composition of claim 11 having an available iodine content of from about 0.5 to about 200 ppm iodine.

16. The composition of claim 11 wherein said diluent is water.

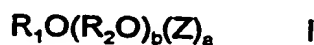
17. The composition of claim 11 wherein said concentrate has a weight ratio of said component (c) to available iodine in said components (a) + (b) of from about 6:1 to about 1:1, respectively.

18. A process for cleaning, sanitizing and disinfecting an intended surface comprising contacting said intended surface with an aqueous antimicrobial use composition containing an iodine complex concentrate and a diluent, said concentrate comprising:

(a) from about 0.5 to about 30% by weight of iodine;

(b) from about 0.2 to about 14% by weight of a component selected from the group consisting of iodide salt, iodide acid and mixtures thereof; and

(c) from about 2% to about 85% by weight of a nonionic sugar surfactant selected from the group consisting of alkyl glucose esters, aldobionamides, gluconamides, glyceramides, glyceroglycolipids, polyglydroxy fatty acid amides, alkyl polyglycosides having the general formula I:



wherein R_1 is a monovalent organic radical having from about 6 to about 30 carbon atoms; R_2 is divalent alkylene radical having from 2 to 4 carbon atoms; Z is a saccharide residue having 5 or 6 carbon atoms; b is a number having a value from 0 to about 12; a is a number having a value from 1 to about 6, and mixtures thereof, all weights being based on the weight of the concentrate.

19. The process of claim 18 wherein said nonionic sugar surfactant is said alkyl polyglycoside.

20. The process of claim 18 wherein said iodide salt is selected from the group consisting of sodium iodide, potassium iodide and mixtures thereof.

10 21. The process of claim 19 wherein b of said general formula I is 0.

22. The process of claim 18 wherein said aqueous antimicrobial use composition has an available iodine content of from about 0.5 to about 200 ppm iodine.

23. The process of claim 18 wherein said diluent is water.

15 24. The process of claim 18 wherein said intended surface is selected from the group consisting of human skin, animal skin, contact surfaces, and glassware.

25. The process of claim 18 wherein said concentrate has a weight ratio of said component (c) to available iodine in said components (a) + (b) of from about 6:1 to about 1:1, respectively.

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/06975

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A01N 59/12.

US CL : 424/667, 669, 670, 671, 672.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 424/667, 669, 670, 671, 672.

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim N .
Y	FAVERO, M.S. 'Sterilization, Disinfection, and Antisepsis in the Hospital.' In: Manual of Clinical Microbiology, 4th ed. Edited by E. H. Lennette et al. Washington, DC: American Society for Microbiology. 1985, page 132.	1-25
Y	US 4,576,818 A (SHETTY) 18 March 1986, see column 1, lines 56-66, from column 2, line 46 to column 4, line 58.	1-25
Y	US 5,266,690 A (MCCURRY, JR. et al.) 30 November 1993, column 3, lines 51-55, column 4, lines 45-62.	1-25

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	* T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
* A* document defining the general state of the art which is not considered to be of particular relevance	* X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
* E* earlier document published on or after the international filing date	* Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
* L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	* &* document member of the same patent family
* O* document referring to an oral disclosure, use, exhibition or other means	
* P* document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search
27 JUNE 1996

Date of mailing of the international search report
15 JUL 1996

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